

Claims:

Having thus described the invention, it is now claimed:

1. A suppository based vaccine delivery system for prophylaxis against or treatment of urogenitally and anorectally transmitted infectious disease in humans and animals, said
5 suppository comprising:

Sub (a) a vaccine or vaccine adjuvant(s) selected from the group consisting of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly-expressed and combinations thereof, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral- or cellular-mediated immunity in humans or animals; and
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(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted into a bodily orifice of a human or animal so as to allow the suppository to be in contact with tissue of the bodily orifice to
15 facilitate transfer of suppository material therethrough.

2. A suppository based vaccine delivery system for prophylaxis against urogenital tract infections in humans, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) selected from the group consisting of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly-expressed and combinations thereof, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans; and
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(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted vaginally so as to allow the suppository to be in contact with vaginal mucous membrane to facilitate transfer of suppository material therethrough.

3. A suppository based vaccine delivery system for prophylaxis against anorectally transmitted infectious disease in humans or animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) elected from the group consisting of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed and combinations thereof, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

(b) suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

wherein the suppository is adapted to be inserted rectally so as to allow the suppository to be in contact with the anorectal mucous membrane to facilitate transfer of vaccine or vaccine adjuvant material therethrough.

4. The suppository based vaccine delivery system of claim 1 wherein the vaccine content or vaccine adjuvant(s) is selected from the group consisting of whole cells, purified

constituents or is generated from known genetic information of urogenital or anorectally transmittable pathogens.

5. The suppository based vaccine delivery system of claim 1 wherein the vaccine
5 or vaccine adjuvant(s) contents are present in the total amount of 10 to 1000 micrograms.

6. The suppository based vaccine delivery system of claim 1 wherein the
suppository base is comprised of polyethylene glycol and polysorbate.

10 7. The suppository based vaccine delivery system of claim 6 wherein the
polyethylene glycol suppository base is comprised of about 75% to about 98% by weight
polyethylene glycol and about 2% to about 25% by weight polysorbate.

15 8. The suppository based vaccine delivery system of claim 6 wherein the
polyethylene glycol has an average molecular weight of about 950 to about 3700.

9. The suppository based vaccine delivery system of claim 6 wherein the
polyethylene glycol suppository base comprises from about 70% to greater than 99% by weight of
the suppository.

20 10. The suppository based vaccine delivery system of claim 1 wherein the
suppository is further comprised of a preservative selected from the group consisting of thimersal,

benzoic acid, benzylkonium, benzylkonium chloride, sulfites, quaternary ammonium salts, chlorobutanol and combinations thereof.

5 *Sub B* 11. The suppository based vaccine delivery system of claim 10 wherein the suppository is further comprised of an emulsifying agent selected from the group consisting of gelatin, methyl cellulose, alginic acid, sodium lauryl sulfate and combinations thereof.

10 *Sub C* 12. A suppository-based vaccine delivery system for prophylaxis against urogenital or anorectally transmitted infections in humans or animals, said suppository comprising:

(a) a vaccine or vaccine adjuvant(s) comprising purified, mutated, synthetic or genetically engineered constituents of known pathogens selected from the group consisting of urogenital pathogens, anorectally pathogens and combinations thereof; and

(b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

15 wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about 950 to about 3700, and wherein the polyethylene glycol suppository base comprises from about 70% to about 99% by weight of the suppository; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the
20 suppository to be in contact with mucous membrane to facilitate transfer of vaccine or vaccine adjuvant(s) material therethrough.

13. A suppository-based vaccine delivery system for prophylaxis against genitourinary or anorectal tract infections in humans or animals, said suppository resulting from the mixture of:

5 (a) a vaccine or vaccine adjuvant selected from the group consisting of whole or fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that consists of nucleic acids, proteins, lipids, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

10 (b) a suppository base, selected from the group consisting of polyethylene glycol, polysorbate and combinations thereof;

15 wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate, wherein the polyethylene glycol has an average molecular weight of about 750 to about 3700, and wherein the polyethylene glycol suppository base comprises from about 70% to greater than 99% by weight of the suppository base; wherein the suppository is adapted to be inserted vaginally or rectally so as to allow the suppository to be in contact with mucous membrane to facilitate transfer of vaccine or vaccine adjuvant(s) material therethrough.

20 14. A method for preventing urogenital or anorectal disease in humans or animals, said method comprising the steps of:

(a) inserting a suppository-based vaccine delivery system into a bodily orifice of a human, wherein said suppository comprises a vaccine or vaccine adjuvant(s) material

comprised of whole, fractionated viral or other microbial pathogens, or their purified cellular constituents, whether native, mutated, synthetic, cloned or recombinantly expressed, that consists of nucleic acids, proteins, other antigenic determinants or combinations thereof capable of producing humoral or cellular-mediated immunity in humans or animals; and

5 (b) contacting the suppository with mucosal tissue at and internal to the bodily orifice to facilitate transfer of the vaccine or vaccine adjuvant material therethrough and induce an immune response in the human.

10 15. The method of claim 14 wherein the protein or nucleic acid originate from the genetic constituents of pathogenic urogenital or anorectally transmissible viruses, other microbes or combination thereof.

15 16. The method of claim 14 wherein the amount of protein, nucleic acids, lipids, other antigenic determinants and combinations thereof are present in the total amount of about 10 to about 1000 micrograms.

Sub 17. The method of claim 14 wherein the polyethylene glycol suppository base is selected from the group consisting of polyethylene glycol, polysorbate and combination thereof.

20 18. The method of claim 17 wherein the polyethylene glycol suppository base is comprised of about 75% to about 98% by weight polyethylene glycol and about 2% to about 25% by weight polysorbate.

The method of claim 18 wherein the polymeric material is about 750 to about 3700.

The method of claim 14 wherein the suppository base is 99% by weight of the suppository base.

Seal 80%

[illegible]